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10/599,307	09/25/2006	Daniel J. Cosgrove	P07504US01 - PHI 1883	6746
27142 7590 01/07/2009 MCKEE, VOORHEES & SEASE, P.L.C. ATTN: PIONEER HI-BRED 801 GRAND AVENUE, SUITE 3200 DES MOINES, IA 50309-2721				
EXAMINER KUBELIK, ANNE R				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

1. Applicant's election without traverse of Group I (claims 1-7, 14, 16-22, 29, 31-37 and 45-51) in the reply filed on 15 October 2008 is acknowledged.
2. The references on the IDS filed 25 September 2006 lined out either because they were not sent or because they are recited on the IDS filed 4 September 2007.

Claim Objections

3. Claims 1, 6-7, 16 and 31-51 are objected to because of the following informalities:

There should a comma before "wherein" in claims 1 and 16, lines 4 and 7, claims 6-7 and 31-51, line 1.

In claims 1 and 16, line 2, --, wherein said method-- should be inserted before "comprising".

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 16, 31-37, 39 and 45-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Neither the instant specification nor the originally filed claims appear to provide support for the recitation of the crop producing a Cry2 protein, as in claims 33-36 and 47-50. There is no mention of Cry2 in the specification.

Neither the instant specification nor the originally filed claims appear to provide support for the recitation of the crop producing a Cry9 protein, as in claims 31-32, 39 and 45-46. There is no mention of Cry9 in the specification.

Neither the instant specification nor the originally filed claims appear to provide support for the recitation of the crop producing a Vip3A protein, as in claims 35-37 and 49-518. There is no mention of Vip3A in the specification.

The only toxins mentioned in the context of planting a mixture of crops, each transformed with a different toxin directed to the same pest are Cry1F, Cry1A(b), Cry34/35 and Cry 3 (see pg 6, lines 8-25).

Neither the instant specification nor the originally filed claims appear to provide support for the recitation of any combinations other than Cry1F with Cry1Ab and Cry34/35 with Cry 3 in claims dependent upon claims 8 and 23. See pg 12, lines 11-18 and original claims 13 and 28.

Thus, such recitations constitute NEW MATTER. In response to this rejection, Applicant is required to point to support for the recitations or to cancel the new matter.

In the preliminary amendment filed 2 August 2007, Applicant urges that support for Cry9 and Cry2 may be found in a patent cited on pg 4, line 2 of the specification, and support for Vip3A may be found in a patent cited on pg 5, line 7-11 of the specification.

This is not found persuasive because there is no such patents cited at those positions in the specification, and the examiner could not find the reference elsewhere. It is noted that

Applicant referred to pg 22 of the specification in the preliminary amendment filed 2 August 2007; however, the specification is only 20 pages long. Applicant may be using a version of the specification with a different pagination.

Pg 4 and 5 of the specification are in the Background of the invention portion of the specification, not the Summary of the invention portion. Reference to toxins only in the Background portion does to provide support for recitation of those toxins in the claims, as they were not mentioned in the Summary portion, which discusses the actual invention.

Lastly, incorporation by reference requires a specific indication of what material is being incorporated. See *Cook Biotech Inc. v. ACell Inc.*, 79 USPQ2d 1865 (Fed. Cir. 2006) at pg 1872

"Incorporation by reference provides a method for integrating material from various documents into a host document ... by citing such material in a manner that makes clear that the material is effectively part of the host document as if it were explicitly contained therein." *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 [54 USPQ2d 1673] (Fed. Cir. 2000) (citations omitted). "To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents." *Id.* (citations omitted). Whether and to what extent material has been incorporated by reference into a host document is a question of law. *Id.*

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 2-3, 14, 17-18 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claims 2 and 17 and are indefinite in their recitation of the abbreviation "ECB", as is not clear to which pest this refers. For purposes of examination, any pest whose name can be abbreviated to these letters was considered.

Claims 3 and 18 are indefinite in their recitation of the abbreviation "WCRW", as is not clear to which pest this refers. For purposes of examination, any pest whose name can be abbreviated to these letters was considered.

Claims 14 and 29 are indefinite in their recitation of the abbreviations "GAT" and EPSPS, as is not clear to which gene this refers. For purposes of examination, any herbicide resistance gene whose name can be abbreviated to these letters was considered.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a), which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1, 4, 16 and 19 rejected under 35 U.S.C. 103(a) as being unpatentable over Zhao et al (2003, Nature Biotechnol. 21:1493-1497).

The claims are drawn to a method of reducing the development of resistant pests in a field of transgenic pest resistant crops, the method comprising planting a blend of two types of transgenic seed, each pesticidal to the same pest but each using a different mode of pesticidal action.

Zhao et al teach a blend of broccoli plants, wherein one plant confers resistance to diamondback moth by way of Cry1Ac and the other by way of Cry1C (paragraph spanning the columns on pg 1494; Fig 1). As there is no linkage between Cry1Ac and Cry1C resistance

genes in diamondback moth (pg 1494, left column, paragraph 1), the CryIAc and CryIC work via different modes of action.

Zhao et al do not teach planting a blend of seeds of the plants.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of preventing insect pests from developing resistance to Bt toxins taught by Zhao et al to plant a blend of seeds. One of ordinary skill in the art would have been motivated to do so because seeds are what farmers would plant in the fields.

10. Claims 5 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhao et al (2003, Nature Biotechnol. 21:1493-1497) as applied to claims 1, 4, 16 and 19 above, and further in view of Pershing et al (2003, US 6,551,962).

The claims are drawn to a method of reducing the development of resistant pests in a field of transgenic pest resistant crops, the method comprising planting a blend of two types of transgenic seed, each pesticidal to the same pest but each using a different mode of pesticidal action, and wherein the seed has been treated with a pesticidal agent.

The teachings of Zhao et al are discussed above. Zhao et al do not teach treating seed with a pesticidal agent.

Pershing et al teach treating seed transformed with a nucleic acid encoding a Cry3Bb protein, which is toxic to ECB and WCRW, optionally with a nucleic acid encoding a second pesticidal protein, with pesticidal agents including pyrethrins, oxadiazines, chloronicotinyls, nitroguanidines, triazoles, organophosphates, pyrrols, pyrazoles, diacylhydrazines and carbamates (column 3, line 38, to column 4, line 10; claims 8-15).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of preventing insect pests from developing resistance to Bt toxins taught by Zhao et al, to treat the seed with a pesticidal agent as described in Pershing et al. One of ordinary skill in the art would have been motivated to do so because Pershing et al teach that the chemical pesticidal treatment would reduce the chance of the pests developing resistance (column 3, line 59, to column 4, line 10).

11. Claims 14 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhao et al (2003, Nature Biotechnol. 21:1493-1497) as applied to claims 1, 4, 16 and 19 above, and further in view of Plaisted et al (1999, US 5,990,395).

The claims are drawn to a method of reducing the development of resistant pests in a field of transgenic pest resistant crops, the method comprising planting a blend of two types of transgenic seed, each pesticidal to the same pest but each using a different mode of pesticidal action and wherein the seed is also transformed with an EPSPS gene.

The teachings of Zhao et al are discussed above. Zhao et al do not teach do not teach seed transformed with an EPSPS gene.

Plaisted et al teach transforming plants with a Cry1Ab gene or VIP3 (now known as the VIP3A) gene, and an EPSPS gene (column 10, line 59, to column 11, line 52).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of preventing insect pests from developing resistance to Bt toxins taught by Zhao et al to also include an EPSPS gene in the seed, given advantages of herbicide resistance touted by Plaisted et al (column 9, line 61, to column 10, line 16).

12. Claims 2-3, 6-7, 17-18, 21-22, 31-37 and 45-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhao et al (2003, Nature Biotechnol. 21:1493-1497) as applied to claims 1, 4, 16 and 19 above, and further in view of each of Crickmore et al (1998, Microbiol. Mol. Biol. Rev. 62:807-813), Plaisted et al (1999, US 5,990,395), Pershing et al (2003, US 6,551,962) and Narva et al (WO 97/40162), taken with the evidence of the instant specification.

The claims are drawn to a method of reducing the development of resistant pests in a field of transgenic pest resistant crops, the method comprising planting a blend of two types of transgenic seed, each pesticidal to the same pest but each using a different mode of pesticidal action and wherein the seed is also transformed with nucleic acids encoding specific Bt toxins.

The teachings of Zhao et al are discussed above. Zhao et al do not teach nucleic acids encoding Cry1F, Cry3, Cry1Ab, Cry2, Cry34Aa1 and Cry35Aa1 or VIP3, nor do they teach mosaics in which one or both seed types of transformed with more than one toxin encoding nucleic acid.

Crickmore et al teach numerous Cry proteins, including Cry1F, Cry3, Cry1Ab and Cry2 proteins (Table 1).

Narva et al teach nucleic acids encoding toxins now known as Cry34Aa1 and Cry35Aa1, which confer resistance to Western corn rootworm (pg 26, lines 10-14, 23-27).

Pershing et al teach treating seed transformed with a nucleic acid encoding a Cry3Bb protein, which is toxic to ECB and WCRW, optionally with a nucleic acid encoding a second pesticidal protein, with pesticidal agents including pyrethrins, oxadizines, chloronicotinyls, nitroguanidines, triazoles, organophosphates, pyrrols, pyrazoles, diacylhydrazines and carbamates (column 3, line 38, to column 4, line 10; claims 8-15).

Plaisted et al teach transforming plants with a Cry1Ab gene or VIP3 gene (now known as VIP3A), and an EPSPS gene (column 10, line 59, to column 11, line 52).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of of reducing the development of resistant pests in a field of transgenic pest resistant crops taught by Zhao et al, to use nucleic acids encoding the Cry toxins described in each of Crickmore et a, Plaisted et al, Pershing et al and Narva et al. One of ordinary skill in the art would have been motivated to do so because selection of one endotoxin over another would be an obvious step in the optimization of a seed/toxin combination that is best suited to a particular environmental setting. The isna nt specification teaches that Cry1F, Cry1Ab, Cry 34/35 and Cry3 all confer resistance to ECB and WCRW (pg 6, lines 17-25).

Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, Ph.D., whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

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Art Unit: 1638

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January 7, 2009

/Anne R. Kubelik/

Primary Examiner, Art Unit 1638